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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/054,889	01/25/2002	Alfred Schaufler	2002-0094A	5466
513	7590	11/10/2003	EXAMINER	
WENDEROTH, LIND & PONACK, L.L.P. 2033 K STREET N. W. SUITE 800 WASHINGTON, DC 20006-1021			MICHENER, JENNIFER KOLB	
			ART UNIT	PAPER NUMBER
			1762	

DATE MAILED: 11/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/054,889	Applicant(s) SCHAUFLE, ALFRED	
	Examiner Jennifer Kolb Michener	Art Unit 1762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-67 is/are pending in the application.
- 4a) Of the above claim(s) 1-20 and 57-67 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-56 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s) _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>11/7/02</u>
<u>6/3/10/03</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statements (IDS) submitted on 11/7/2002 and 3/10/2003 are being considered by the examiner. It appears that some additional copies of references, not cited on these IDSs, are present in the case. If an additional IDS was submitted by Applicant and not considered by Examiner herein, it is suggested that an additional copy be sent for consideration.

Election/Restrictions

2. Applicant's election of Group III, claims 21-56, is acknowledged. No traversal has been made, therefore Examiner interprets this election to be without traverse.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 21-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The use of the phrase "Folk Ward" is unclear. It is not clear whether the diameter taken by a different method would be equally operational. For the purposes of examination, Examiner interprets the claim to require the given average diameter.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 21-24, 26-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zimmerman US Pat. 4,453,939.

Zimmerman et al. teach a method of coating a carrier with a suspension comprising fibrinogen and thrombin by providing fibrinogen in alcohol and thrombin in alcohol, mixing the two, and coating onto a carrier (Example 2; col. 3, line 1 and line 17).

Zimmerman teaches the use of fibrinogen and thrombin particles, in particularly "fine particles" (example 8), however the reference fails to teach a specific particle diameter.

It is Examiner's position that selection of an optimal particle size would have been evident to one of ordinary skill in the art. Particle size determines the relative surface area and thus reactivity. Depending on how quickly the particles are required to react in the body to form a clot, an ordinary artisan would select an appropriate particle size.

It is well settled that determination of optimum values of cause effective variables such as these process parameters is within the skill of one practicing in the art. *In re Boesch*, 205 USPQ 215 (CCPA 1980).

Regarding claims 22-23, Zimmerman teaches the use of a collagen carrier in the form of a foam or sponge (col. 2, line 21; example 4).

Regarding claims 26-28, Zimmerman teaches preparation of the thrombin and fibrinogen mixtures at exemplary temperatures of 0-4 °C, overlapping the ranges claimed by Applicant, with application occurring just 30 seconds later, and subsequent evaporation and storage occurring under refrigerated conditions. It is evident that Zimmerman desires to maintain cooled temperatures. Additionally, it is Examiner's position that in the 30 seconds between preparation and application, the temperature remains, for all intents and purposes, within the range claimed by Applicant.

Overlapping ranges are *prima facie* evidence of obviousness. It would have been obvious to one having ordinary skill in the art to have selected the portion of Zimmerman's range that corresponds to the claimed range. *In re Malagari*, 184 USPQ 549 (CCPA 1974).

Regarding claims 29-30, Zimmerman fails to teach the humidity of the application environment. However, it is Examiner's position that selection of a suitable humidity would have been within the skill of an ordinary artisan because humidity, like

Art Unit: 1762

temperature and pressure, impacts reaction and evaporation rates. It would have been obvious to one of ordinary skill in the art to select a humidity suitable for the application process of Zimmerman. Determination of optimum cause-effective variables is obvious for those reasons outlined above. Additionally, Examiner notes that the humidities claimed are normal summertime humidities for our region, which would inherently meet Applicant's claims in the absence of any special procedures taken to alter the humidity within the workplace.

Regarding claim 31, Zimmerman provides exemplary quantities of thrombin and fibrinogen, in mg, per cm^2 of collagen foam surface, but does not provide this data in ml of suspension per cm^2 of collagen foam surface, as required by Applicant. This calculation could be made based on the amount of solvent used, however, Zimmerman merely teaches the use of a "sufficient" amount. Therefore, Zimmerman teaches that selection of concentration per unit area is important, however, Examiner is unable to determine if the concentration in mg/area overlaps the concentration required by Applicant in mL/area . Therefore it is Examiner's position that because Zimmerman the importance of concentration that it would have been obvious to an ordinary artisan to optimize concentration to provide a desired amount of clotting in the given area of the coated carrier. Optimization of cause effective variables would have been obvious for those reasons outlined above.

Regarding claims 32-40, Zimmerman teaches application of the coating suspension by spraying (col. 3, line 6). It is well-known in the coating art to apply coatings uniformly to maximize their effectiveness. A uniform coating in this art will yield clotting that is substantially the same over the entire surface of the carrier. Spraying necessarily requires a jet, however, Zimmerman fails to teach the use of multiple jets or nozzles, relative movement of the carrier and nozzle, and the flow rate of the suspension. However, it is Examiner's position that it is well-known in the coating art that spray-coating a uniform coating, whether on cars or furniture or medical devices, requires relative movement of the coater and substrate to access all areas of the object to be coated. It would have been obvious to one of ordinary skill in the art to move the coater relative to the substrate to provide a uniform coating. Selection of optimized flow rates and rates of movement would have been within the skill of an ordinary artisan for those reasons outlined above based on the speed desired for completing the coating operation and the capabilities of the spray coater.

Regarding claim 24, the carrier of Zimmerman is collagen and thus expected to be 100% collagen.

Regarding claim 41, Zimmerman teaches the use of a vacuum to dry the coating surface on the carrier, which fixates the coating (col. 3, line 9). While Zimmerman does not teach the exact pressure of the vacuum, it is Examiner's position that a vacuum would be the range falling below 1 atm or 1013 mbar. Applicant requires the use of a

pressure of less than 1000 mbar, which is to say, Applicant requires at least a slight vacuum. Examiner notes that Zimmermans range would therefore overlap the range claimed by Applicant of less than 1000 mbar. Overlapping ranges are obvious for those reasons outlined above.

8. Claims 25 and 42-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zimmerman in view of Cioca et al. (3,939,831) and Koken Co. (3/7/1995 unexamined publication).

Zimmerman teaches the use of a collagen sponge foam as the carrier for the above suspension, but fails to teach the specifics of such a sponge.

Cioca teaches that it is known in the prior art to create a porous collagen sponge for use as skin dressing by introducing air to foam the collagen (col. 1), after which the collagen inherently dries and contains pores.

Koken Co. teaches that a suitable air bubble pore within collagen sponges for use as skin wound covers is 50-2000 μm , overlapping the ranges claimed by Applicant.

Since Zimmerman teaches the use of foamed porous collagen and Cioca and Koken Co. teach the appropriate means of producing such an article and the appropriate pore size, Cioca and Koken Co. would have reasonably suggested the use of collagen with the pore size of Koken Co. made by the method taught by Cioca in the method of Zimmerman. It would have been obvious to one of ordinary skill in the art to use the teachings of Cioca and Koken Co. to provide suitable properties of a collagen foam for use as a wound dressing.

The pore size and method of producing foam are also applicable to certain aspects of claim 42. The remaining aspects of claim 42 regarding the suspension application have been addressed above in the Zimmerman reference.

Likewise the limitations of claims 43-47 have also been addressed above.

Since no vacuum is complete, some air will pass across the surface, as required by claim 48.

Regarding claims 49-51, as outlined above, the suspensions of Zimmerman are kept at the cool temperatures required by Applicant before application. Additionally, Zimmerman teaches refrigeration during evaporation and during storage, although the exact temperatures are not given. Since it is known that thrombin and fibrinogen denature in alcohol unless kept cool, it is Examiner's position that it would have been within the skill of an ordinary artisan to maintain the exemplary temperatures taught by Zimmerman throughout the evaporation step to avoid denaturization of the thrombin and fibrinogen. Additionally, selecting an appropriate amount of time required for evaporation at such temperatures would have been within the skill of an ordinary artisan based on the amount of alcohol solvent used and the degree of vacuum employed. Selection of optimum variables would have been within the skill of an ordinary artisan for those reasons outlined above.

Regarding claims 52-53, it appears to Examiner that Zimmerman coats the entire substrate.

Regarding claims 54-55, Zimmerman teaches the substantial absence of water (col. 3, line 59).

Regarding claim 56, Example 1 of Zimmerman teaches the further use of aprotinin.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Hagedorn et al. (5,942,278) teaches suspension of fibrinogen and thrombin in alcohol for application to a collagen carrier for wound treatment. Kosow (WO 97/28832) teaches suspension of fibrinogen and thrombin in alcohol for application to the carrier for wound treatment (page 6).

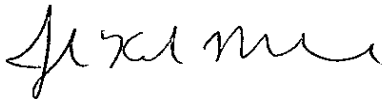
10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kolb Michener whose telephone number is 703-306-5462 until December, at which point the new number will become 571-272-1424. The examiner can normally be reached on Monday through Thursday and alternate Fridays.

Application/Control Number: 10/054,889
Art Unit: 1762

Page 10

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shrive P. Beck can be reached on 703-308-2333. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

A handwritten signature in black ink, appearing to read 'J Kolb Michener', with a stylized, cursive script.

Jennifer Kolb Michener
Patent Examiner
Technology Center 1700
November 3, 2003